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First Things, First: A Principled Approach to Patent Administrative Law

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FIRST THINGS, FIRST: A PRINCIPLED APPROACH TO PATENT ADMINISTRATIVE LAW

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ABSTRACT

This Article, using the controversy over continuation practices at the heart of *Tafas v. Dudas*, examines the impact of patent exceptionalism on the development of patent administrative law. In particular, this Article explores the way in which the Federal Circuit's opinion in *Merck v. Kessler* can be used to (temporarily) resolve tensions in how Section 2 of the Patent Act is interpreted with respect to substantive rulemaking. After this initial review, this Article attempts to outline a series of "first principles" that may be useful in resolving the underlying tensions over agency decision-making in this area. This Article contemplates two useful principles that might clarify how to resolve controversies over agency decision-making in patent law. First, the USPTO's policy-making must be reconciled with standard administrative doctrine. The term "reconciled" is used deliberately to refer to the process of accommodating the unique demands of patent law to the administrative state. This is particularly important in light of the increased range of agency decision-making contemplated by recent patent reform efforts. Second, any process of reconciliation must recognize and account for the impact of third party participation that will arise from stronger administrative action. Outlining these "first principles" takes on significant importance given the

* Assistant Professor, Marquette University Law School. This Article is dedicated to my circle of friends—Cristina Posa, Alana Murray, Maya Kulcyky, Heather Davis, Kia Settles, Tennille Holland, Cescili Hopkins, Lanae Shelton, Tovah Calderon, Cicely Vaughn-White, Abi Nkwa, Erica Rossi, Mercedes Caravello, Nadelle Grossman, Natalie Wisniewski, Christiane Pollman, Pamela Orsak, Amy Hoang-Wrona, Julie Waterstone, Cary Cluck, Jacqueline Serrao, Kristi Bowman, E. Farish Percy, Kathryn Reuther, Ellen Asfar, Kathyrn Evans-Ombam and Maria Maroulis—since wherever you are I am at home. I would also like to thank the 2009 Drake Intellectual Property Scholars Roundtable for the opportunity to present this paper in its early stages as well as my colleagues, Dean Joseph Kearney, Associate Dean Micheal O'Hear, and Bruce Boyden for their thoughtful comments. Finally, I would like to thank my research assistants, Jonathan Cattey and Sammi-Jo Nevin for their able assistance.

"re-defining" moment associated with current patent reform.

I. INTRODUCTION

On August 22, 2007, Dr. Triantafyllos Tafas sued the United States and Patent Trademark Office ("USPTO") over its newly issued rules that limited the number and content of what are termed continuation applications that can be filed by a patentee.[1] An interest group or individual suing an agency in federal court over a newly issued rule is an everyday occurrence in administrative law. *Tafas v. Dudas*,[2] however, has been treated as an unusual occurrence in patent law, already provoking substantial academic and practitioner commentary. Treating *Tafas* as an unusual case obscures what makes it an *important* case for the development of a patent administrative law.

This Article, then, has two goals. Initially, I seek to outline the particular importance of *Tafas* in usefully marking another moment where the debate over "patent exceptionalism" in administrative law is particularly explicit. *Tafas* offers another opportunity to reject such exceptionalism in another area: the question of judicial review of the interpretative decision-making of the USPTO.[3] Such exceptionalism is not useful in addressing the problems created by a significant growth in a "politics" of patent law.

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1. Complaint at 1-3, Tafas v. Dudas, No. 1:07-cv-846-JCC/TRJ, 2007 WL 3359672, (E.D. Va. Apr. 1 2008); *see also* Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (reporting the proposed rule change). On October 17, 2007, Judge Cacheris consolidated *Tafas* with another case brought by SmithKline Beecham Corporation, and Glaxo Group Limited, GlaxoSmithKline d/b/a ("GSK"). Tafas v. Dudas, 530 F. Supp. 2d 786, 791 (E.D. Va. 2008) (reporting the date of consolidation in an order denying plaintiff's motion to compel discovery). Subsequent citations will reflect the fact that the parties submitted different pleadings throughout the rest of the case.

2. 541 F. Supp. 2d 805 (E.D. Va. 2008).

3. Rejecting such patent exceptionalism within the context of administrative patent law has been the keen focus of much scholarship in this area. *See, e.g.*, William J. Blonigan, *Road Work Under Construction: Administrative Claim Interpretations and the Path of Greater Deference from The Federal Circuit to the Patent Office*, 35 AIPLA Q.J. 415, 422-24 (2007) (criticizing failure to accord deference to agency decision-making over claim construction); Stuart M. Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 294-301 (2007) (criticizing failure of the Federal Circuit to appropriately defer to agency interpretative choices); Craig A. Nard, *Deference, Defiance and the Useful Arts*, 56 OHIO ST. L.J. 1415, 1416-23 (1995) (criticizing the failure of the Federal Circuit to use *Chevron* deference within the context of interpretations issued by the Board of Patent Appeals and Interferences).

If a retreat from patent exceptionalism in administrative law is possible, then I next contemplate two useful principles that might clarify how to resolve future controversies over interpretative agency decision-making in patent law. First, the USPTO's policy-making must be reconciled with standard administrative doctrine. The term "reconciled" is used deliberately to refer to the process of accommodating the unique demands of patent law to the administrative state. This is particularly important in light of the increased range of agency decision-making contemplated by recent patent reform efforts. Second, any process of reconciliation must recognize and account for the impact of third party participation that will arise from stronger administrative action. Outlining these "first principles" takes on significant importance given the re-defining moment associated with the current patent reform.

II. *TAFAS* AND THE PROBLEM OF PATENT EXCEPTIONALISM IN ADMINISTRATIVE LAW

Tafas involves the attempt by the USPTO to limit the ability of patent owners to file what is known as a "continuation application," which allows the patentee to continue prosecuting a patent application if the continuation application is: (1) filed before patenting, abandonment, or termination of the previous application; and (2) contains or is amended to contain a specific reference to an earlier application.[4] The USPTO conducted this rulemaking under 35 U.S.C. Section 2 (b)(2)(A)-(B) so as to correct perceived abuses in continuation application practice.[5] Section 2(b)(2)(A)-(B), in relevant part, states that: "[t]he Office . . . may establish regulations, not inconsistent with law, which (A) shall govern the conduct of proceedings in the Office; [and] (B) shall be made in accordance with section 553 of title 5."[6] The text of the Section 2(b)(2)(A) incorporates textual language from a predecessor provision, Section 6.[7] Congress amended the former Section 6 in 1999 to expand the USPTO's administrative responsibility in a number of areas. The new Section 2 included the text of the former Section 6 as well as a number of new provisions.[8]

4. 35 U.S.C.A. § 120 (West 2009). *Tafas*, 541 F. Supp. 2d at 808-09.

5. 35 U.S.C.A. § 2(b)(2)(A)-(B) (West 2009).

6. *Id.*

7. *Compare* 35 U.S.C.A. § 2 , *with* Patent Act of 1952, Pub. L. No. 593-950, § 6, 66 Stat. 792, 793 (1952) (reflecting that the current Section 2 incorporated aspects of the old § 6). *See infra* note 113 and accompanying text (quoting the language of Section 6 of the 1952 Patent Act).

8. Patent and Trademark Office Efficiency Act, Pub. L. No. 106-113, 113 Stat. 1501, 1501A-572 to -75 (1999) (codified as amended at 35 U.S.C.A. § 2.

After receiving over three hundred forty-three comments from intellectual property organizations, government agencies, corporations and individuals,[9] the USPTO issued the rules, entitled "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications" on August 21, 2007.[10] The rules had three key components. First, the rules limited the number of continuation, continuation-in-part, and a request for continued examination applications and that could be filed by a patentee without justification to two sets of applications.[11] The rules required that once these limits had been exceeded, the patentee would have to justify any additional submission of a continuation, a continuation-in-part, or request for continued examination application.[12] Second, in a similar vein, the rules limited the number continuation applications that could be filed within the same divisional family.[13] Third, the rules required the patentee to provide additional information if the patentee filed more than five independent claims or more than twenty-five total claims.[14] The rule proved remarkably controversial as limiting such claims could prevent owners from amending their claims in an unrestricted manner during the course of a prosecution.

Upon review of a temporary restraining order and preliminary injunction submitted by GlaxoSmithKline ("GSK"), Judge James C. Cacheris issued a preliminary injunction on October 31, 2007, holding that GSK had demonstrated: (1) a likelihood of success on the merits since the Final Rules were potentially substantive in nature,[15] and moreover, did not properly interpret Section 120;[16] (2) irreparable harm given the potential uncertainty associated with patent property rights that would accompany the suggested limits on continuation practice;[17] (3) irreparable harm associated with the rules would be greater than

9. Comments on Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, Notice of Proposed Rulemaking, http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/continuation_comments.html (last visited Feb. 21, 2009).

10. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

11. *Id.* at 46,716-18.

12. *Id.*

13. *Id.*

14. *Id.*

15. Tafas v. Dudas, 511 F. Supp. 2d. 652, 664 (E.D. Va. 2007).

16. *Id.* at 665.

17. *Id.* at 669.

any administrative difficulties faced by the USPTO if a delay in issuance was imposed;[18] and (4) implementing the rules would be permanently harmful to patent owners because the Final Rules potentially undermined the stability of property rights in patents.[19] After substantive briefing of the issues by the parties (which was accompanied by the admission of at least thirty-eight amicus briefs),[20] Judge Cacheris issued a decision on April 1, 2008.[21] In the decision, Judge Cacheris granted summary judgment to Tafas and GSK under Section 706(2) of Administrative Procedure Act ("APA"),[22] holding that the USPTO had not acted in "accordance with [the] law" and "in excess of its statutory jurisdiction [and] authority" by undertaking a "substantive rulemaking" under Section 2(b) of the Patent Act.[23] The USPTO appealed this decision to the United States Court of Appeals for the Federal Circuit on May 1, 2008.[24]

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18. *Id.* at 669-70.

19. *Id.* at 670.

20. The following parties submitted amicus briefs: Pharmaceutical Research and Manufacturers of America, Biotechnology Industry Organization, Elan Pharmaceuticals, Inc., American Intellectual Property Law Association, Monsanto Company, William Mitchell College of Law, Intellectual Property Policy Institute, Human Genome Sciences, Inc., Polestar Capital Associates, LLC, Norseman Group, LLC, Public Patent Foundation, Computer and Communications Industry Association, AARP, Consumer Federation of America, Essential Action, Foundation for Taxpayer and Consumer Rights, Initiative for Medicines, Access and Knowledge, Knowledge Ecology International, Prescription Access Litigation, Public Knowledge, Research on Innovation, Software Freedom Law Center, CFPH LLC, CropLife America, Micron Technology, Inc., Federation Internationale Des Conseils En Proprit Industrielle, AmberWave Systems Corp., Fallbrook Technologies Inc., InterDigital Communications LLC, Nano-Terra Inc., Tessera, Inc., BioAdvance, Washington Legal Foundation, Life Sciences Greenhouse of Central Pennslyvania, Pittsburgh Life Sciences Greenhouse, Intellectual Property Owners Association, Ron D. Katznelson, Teles AG Infromationstechnologien, Intellectual Property and Administrative Law and Public Health Professors, Bar Association of the District of Columbia and Robert Lelkes. *See* Justia.com Federal District Court Filings & Dockets, *Tafas v. Dudas*, (E.D. Va., filed Aug. 22, 2007) (No. 1:07-cv-846-JCC/TRJ) *available at* http://dockets.justia.com/docket/court-vaedce/case_no-1:2007cv00846/case_id-221151/ (listing groups who filed amicus briefs).

21. *Tafas,* 541 F. Supp. 2d at 805.

22. *See* Administrative Procedure Act, 5 U.S.C.A. § 706(2)(A),(C) (West 2009) (stating that "[t]he reviewing court shall . . . (2) hold unlawful and set aside agency action, findings and conclusions found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;" and "(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right").

23. *Tafas*, 541 F. Supp. 2d. at 811.

24. Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008), *appeal docketed*, No. 08-1352 (Fed. Cir. May 8, 2008). Oral argument was held on December 5, 2008. Tafas v. Dudas, No. 08-1352 (Fed. Cir. argued Dec. 5, 2008).

Why has *Tafas*, more so than other recent patent administrative cases, such as *Star Fruits SNC v. United States*[25] (a case which addressed whether examiner decisions could be appealed under the APA) captured the regulated public's imagination? One answer is that *Tafas* embodies a number of emerging trends in the current moment in American patent law such as: (1) ongoing frustration with the administrative efficiency of the USPTO; (2) the split in the regulated patent community between companies, such as pharmaceutical and engineering corporations that support a "strong" patent right, versus companies such as computer and software industries that support a "weaker" patent right; and (3) the emerging power of advocate groups seeking to advance patent policy in the name of a "public interest." An equally important answer, however, is the importance of the underlying legal issue in the case: should judicial review of interpretative agency decision-making within the patent context differ from review in other administrative contexts (such as environmental law)? Or, as expressed in simpler terms: is patent law "exceptional" within administrative law? This Section uses *Tafas* as a lens to explore the bases for patent exceptionalism, first by exploring the parties' paradigms as laid out in their relevant submissions, and then, by exploring *why* such exceptionalism has arisen in patent law.

A. Tafas*: the New Normal in Patent Administrative Law*

Thomas Kuhn, famously, in *The Structure of Scientific Revolutions*,[26] described the process of scientific discovery as a cyclical one wherein the "normal science"[27] of a given scientific field, faced with growing anomalies in understanding a given concept, is gradually or sometimes abruptly, replaced with a radically different explanation for that same phenomena.[28] Kuhn termed this process "paradigm change."[29] Kuhn's description of paradigm shift offers a useful perspective as to why *Tafas* has proved so compelling to regulated constituencies. It marks a moment when the "normal" perspective on the USPTO as a relatively "weak" administrative actor gives way to a perspective that seeks a stronger role of the USPTO.

The plaintiffs in *Tafas*—Dr. Tafas and GSK—presented the

25. 393 F.3d 1277, 1284-85 (Fed. Cir. 2005) (explaining that examination demands, made pursuant to regulations, must be deferred to unless such demands are arbitrary and capricious).

26. THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (2d ed. 1970).

27. *Id.* at 24.

28. *Id.* at 52-66.

29. *Id.* at 66.

standard paradigm: the USPTO is a weak administrative actor, hemmed in by congressional limits on its power outlined in Section 2 of the Patent Act.[30] The USPTO argued otherwise, emphasizing that the USPTO acts like any other administrative actor, with a range of strong interpretative options to conduct its agency mission.[31] Notably, the district court in *Tafas* re-affirmed the standard paradigm, seeking continuity rather than radical change in the ways in which the USPTO's power can be interpreted.

1. The Plaintiffs' Paradigm: A "Bound" Administrative Actor

The consolidated plaintiffs' core arguments in *Tafas* are straightforward, and remained so on appeal.[32] First, the USPTO did not issue interpretative rules as the USPTO initially asserted in the text of the rules themselves, and therefore, were not insulated from judicial review under Section 553 the Administrative Procedure Act.[33] Second, if the USPTO did conduct a "notice and comment" rulemaking under Section 553 of the Administrative Procedure Act, then it was without authority to do so since Section 2 limits the authority to conduct a rulemaking on substantive issues.[34] This particular argument relied on the Federal Circuit's holding in *Merck & Co. v. Kessler*[35] in a narrow fashion.

In *Merck*, the Federal Circuit considered whether the change in how patent terms were calculated (from seventeen years from the date of issuance to twenty years from the date of filing) under the Uruguay Round Agreements Act would impact those pharmaceutical patents whose term had been granted a

30. Plaintiff Triantayllos Tafas' Memorandum of Law in Support of Summary Judgment Motion at 14-15, Tafas v. Dudas, 541 F. Supp. 2d. 805 (E.D. Va. 2008) (No. 1:07-cv-846-JCC-TRJ) [hereinafter Tafas Summary Judgment Memo].

31. *Id.* at 10.

32. *Id.* at 5-10; Brief for Plaintiff-Appellee Triantafyllos Tafas at 10-11, Tafas v. Dudas, No. 2008-1352 (Fed. Cir. filed Sept. 24, 2008) [hereinafter Tafas Appellee Brief]; Brief of Plaintiffs-Appellees Glaxosmithkline at 9-10, Tafas v. Dudas, No. 2008-1352 (Fed. Cir. filed Sept. 24, 2008) [hereinafter GSK Appellee Brief].

33. Section 553 exempts "interpretative rules, general statement of policy, or rules of agency organization, procedure or practice." 5 U.S.C.A. § 553(b)(3)(A) (West 2009); Tafas Summary Judgment Memo, *supra* note 30, at 8-10; Tafas Appellee Brief, *supra* note 32, at 14-15; GSK Appellee Brief, *supra* note 32, at 9-13.

34. Tafas Summary Judgment Memo, *supra* note 30, at 8-11; Memorandum in Support of Glaxosmithkline's Motion for Summary Judgment at 17-20, Tafas v. Dudas, 541 F. Supp. 2d. 805 (E.D. Va. 2008) (No. 1:07-cv-846-JCC-TRJ).

35. 80 F.3d 1543 (Fed. Cir. 1996).

restoration extension under the Hatch-Waxman Act.[36] The court held that those pharmaceutical patents filed before June 8, 1995 were entitled to restoration extension to a twenty year filing term, except those patents that were protected as of the same date only because of the restoration extension under the Hatch-Waxman Act.[37] In its decision in *Merck*, the Federal Circuit examined whether to give deference to an interpretation issued by the USPTO.[38] In doing so, the court noted that Congress had not granted the USPTO the authority to undertake what it termed substantive rulemaking.[39]

In light of *Merck*, the consolidated plaintiffs argued that the USPTO did not have the power to undertake the regulations at stake in *Tafas*.[40] The consolidated plaintiffs' argument reflected the traditional understanding of the USPTO's administrative powers. According to such a view, the USPTO does not exercise the same authority as other administrative actors because it is bound by Congressional constraints. The "bound" administrative actor is then denied the flexibility associated with other administrative actors.

2. *The Government's Paradigm: A "Free" Administrative Actor*

In a sense, the USPTO' briefs, submitted both at the trial[41] and appellate[42] level, are quite standard for government agency briefs. Both sets of briefs emphasized that the rules at issue should be understood within the context of *Chevron USA, Inc. v. NRDC, Inc.*.[43] In *Chevron*, the Supreme Court articulated what has become known as the famous *Chevron* "two-step" inquiry in which a court, faced with judicial review of an agency interpretation of a statue, examines: (1) "whether Congress has directly spoken to the precise question at issue," which has been interpreted to mean that congressional intent is "clear" and "unambiguously expressed"; and (2) if statutory ambiguity does exist, "whether the agency's answer is based on a permissible

36. *Merck*, 80 F.3d at 1546.
37. *Id.* at 1550-51.
38. *Id.* 1549-50.
39. *Id.*
40. Tafas Summary Judgment Memo, *supra* note 30, at 14-16.
41. Memorandum in Support of Defendants' Motions for Summary Judgment, Tafas v. Dudas, 541 F. Supp. 2d. 805 (E.D. Va. 2008) (No. 1:07-cv-846-JCC-TRJ) [hereinafter USPTO Summary Judgment Memo].
42. Brief for Appellants, Tafas v. Dudas, No. 2008-1352 (Fed. Cir. filed Sept. 24, 2008) [hereinafter USPTO Appellant Brief].
43. 467 U.S. 837 (1984); USPTO Summary Judgment Memo, *supra* note 41, at 20-23; USPTO Appellant Brief, *supra* note 42, at 11-13.

construction of the statute."[44]

In *Tafas*, the USPTO attempted to place its actions into a standard *Chevron* framework. The briefs emphasized four sets of interlocking premises: (1) Section 2 of the Patent Act expressly grants statutory authority to the USPTO;[45] (2) the USPTO conducted such a rulemaking under Section 2;[46] (3) the statutory text in question, 35 U.S.C. Section 120 was ambiguous since the Act fails to articulate the number and content of continuation applications;[47] and (4) therefore, deference was owed to any interpretative choices undertaken by the USPTO.[48]

A key aspect of the government's attempt to reframe this debate as a standard administrative law debate was both briefs' re-reading of *Merck*. Instead of using *Merck* as a guide to how to read a constrained Section 2 (and its predecessor Section 6), the government emphasized a less remarked upon aspect of *Merck*.[49] The administrative action at stake in *Merck* was a policy statement, entitled a "Final Determination."[50] Thus, the governmental briefs attempt to "re-read" *Merck* to insist that the lack of deference afforded the USPTO came not from a rather constrained view of the USPTO's Section 2 powers, but because the USPTO choose to issue its interpretations in a less formal manner and therefore, was owed less deference.[51]

The ambiguous language of Section 2, however, potentially undermines the government's primary argumentative premise (upon which all of its other premises rest) that the USPTO has express authority to administer its statute. The key phrase of Section 2—that the USPTO has the ability to "govern the conduct of proceedings in the Office"[52] appears to narrow the areas in which the USPTO can be said to administer the statute. It may, however, not particularly preclude administration entirely (as argued by GSK in its reply to the government briefs in the district

44. *Chevron*, 467 U.S. at 842-43.

45. USPTO Appellant Brief, *supra* note 42, at 18, 24-28; USPTO Summary Judgment Memo, *supra* note 41, at 20.

46. USPTO Appellant Brief, *supra* note 42, at 18, 24-28; USPTO Summary Judgment Memo, *supra* note 41, at 20.

47. USPTO Appellant Brief, *supra* note 42, at 22-23; USPTO Summary Judgment Memo, *supra* note 41, at 17-18.

48. USPTO Appellant Brief, *supra* note 42, at 22-23; USPTO Summary Judgment Memo, *supra* note 41, at 17-18.

49. USPTO Appellant Brief, *supra* note 42, at 22-23; USPTO Summary Judgment Memo, *supra* note 41, at 17-18.

50. *Merck*, 80 F.3d at 1548; USPTO Appellant Brief, *supra* note 42, at 22-23; USPTO Summary Judgment Memo, *supra* note 41, at 17-18.

51. USPTO Appellant Brief, *supra* note 42, at 22-23; USPTO Summary Judgment Memo, *supra* note 41, at 17-18.

52. 35 U.S.C.A. § 2(b)(2)(A).

court).[53]

Thus, the text of Section 2 presents a difficult analytical problem because the Federal Circuit will ultimately have to confront what has been termed by Thomas Merrill and Kristin Hickman as "step zero" of the *Chevron* framework: the determination of exactly what type of administrative authority Congress intended to delegate to the USPTO.[54] Merrill and Hickman contend that "[w]ith respect to 'ordinary' gaps in a statutory scheme, *Chevron* represents a presumption that Congress intends the agency to be primary interpreter. It does not follow, however, that Congress harbors the same intent with respect to 'extraordinary gaps' that implicate the scope of an agency's authority."[55] The question of whether *Chevron* deference applies to an agency's assessment of its authority to properly administer its enabling statute is the subject of significant controversy. Indeed, a circuit split has developed over whether to accord such deference to an agency's interpretation of its jurisdictional authority.[56] Notably, *Merck* itself has been interpreted to demonstrate a circumstance in which *Chevron* deference is not accorded to an agency's interpretation of its jurisdictional authority.[57]

In the *Tafas* district court proceedings, neither party fully engaged with this *Chevron* "step zero" inquiry, although the USPTO's brief referred to other provisions of Section 2 and other procedural provisions of the Patent Act to strengthen its argument that Congress has delegated considerable authority to the USPTO

53. Glaxosmithkline's Opposition to Defendants' Motion for Summary Judgment Against the "Glaxosmithkline" Plaintiffs at 5-7, 541 F. Supp. 2d 805 (E.D. Va. 2008) (No. 1:07-cv-846-JCC-TRJ).

54. Thomas W. Merrill & Kristin E. Hickman, *Chevron's Domain*, 89 GEO. L.J. 833, 912-13 (2000).

55. *Id.*; *see also* Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187, 212-19 (2006) (analyzing the modified *Chevron* framework and proposing potential ways to reduce its problems).

56. *Compare* N. Ill. Steel Supply Co. v. Sec'y of Labor, 294 F.3d 844, 846-47 (7th Cir. 2002) (stating that *Chevron* deference is not given to agency's interpretation of its jurisdictional authority), *with* Me. Pub. Util. Comm'n v. FERC, 520 F.3d 464, 479 (D.C. Cir. 2008) (holding that an agency interpretation of its jurisdictional authority is given *Chevron* deference); EEOC v. Seafarers Int'l Union, 394 F.3d 197, 201 (4th Cir. 2005) (finding *Chevron* deference applicable when interpreting EEOC's statute). For further discussion of these issues, *see* Melissa Berry, *Beyond Chevron's Domain: Agency Interpretations of Statutory Procedural Provisions*, 30 SEATTLE U. L. REV. 541, 544-45 (2007) (outlining courts' disagreement over jurisdictional grants of authority).

57. *See* Lars Noah, *Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law*, 41 WM. & MARY L. REV. 1463, 1517 (2000) (explaining that *Chevron* deference is not given to an agency's interpretation of its enabling statute when the ambiguity involves the scope of jurisdiction).

to administer the Patent Act.[58] In particular, the Government's briefs referred to: (1) 35 U.S.C. Section 3(a)(2)(A), which outlines the duties of the Director of the Office;[59] (2) 35 U.S.C. Section 2 (b)(2)(C), which outlines the ability of the USPTO to facilitate the processing of patent applications;[60] and (3) 35 U.S.C. Section 132(b), which outlines the ability of the Director to issue regulations that allow for continued examination of the patent.[61]

Before the district court, the governmental briefs tried to strengthen the alternative vision of agency interpretative power that relies on using Section 2 as one textual element among many that constitute the USPTO's power to administer the Patent Act.[62] The major refinements of both sides' appellate briefs (as opposed to the briefs submitted to the district court), is that both parties more fully engage the *Chevron* "step zero" problem at the heart of *Tafas*. For instance, the brief submitted by GSK emphasizes that Congress has not granted the "*Chevron* Step Zero" authority to the USPTO, and so any deference to its authority is not warranted.[63] In support of its position, GSK contends that: *Merck* implicitly adopted the position of the Seventh Circuit, which does not grant *Chevron* deference to an agency's interpretation of its jurisdictional authority,[64] and furthermore, Congress ratified this decision by not expanding the scope of the USPTO's authority in 1999 (when it revised the pre-existing Section 6).[65] By contrast, the USPTO's reply brief emphasized two themes. First, the USPTO brief pointed to a competing line of circuit authority, which states that an agency's interpretation of its jurisdictional authority is accorded *Chevron* deference.[66] Second, although the government did not explicitly raise its inter-textual argument from below, it did attempt to use the Federal Circuit's recent holdings

58. USPTO Summary Judgment Memo, *supra* note 41, at 13-29.

59. *See* 35 U.S.C.A. § 3(a)(2)(A) (stating that "[t]he Director shall be responsible for providing policy direction and management supervision for the Office and for the issuance of patents").

60. *See* 35 U.S.C.A. § 2(b)(2)(C) (explaining that "[t]he Office . . . shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically, subject to the provisions of section 122 relating to the confidential status of applications").

61. *See* 35 U.S.C.A. § 132(b) (West 2009) (proscribing that "[t]he Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant").

62. USPTO Summary Judgment Memo, *supra* note 41, at 13-29.

63. GSK Appellee Brief, *supra* note 32, at 14-24.

64. *Id.* at 20-21.

65. *Id.* at 24-25.

66. USPTO Appellant Brief, *supra* note 42, at 21-22; *see supra* note 55 (reporting the circuit split; listing the circuit's that accord *Chevron* deference to an agency's jurisdictional determination).

in *Cooper v. Dudas*,[67] *Lacavera v. Dudas*,[68] and *Bender v. Dudas*[69] to support its inter-textual position.[70]

If the *Chevron* deference framework is not available to analyze the rulemaking, then, the question is asked: what deference is owed at all? The USPTO's brief (briefly) offers the *Skidmore* persuasiveness framework as an alternative deferential framework to the standard *Chevron* deference framework.[71] The government contends that rulemakings conducted under Section 2 should be analyzed under the persuasiveness standard outlined in *Skidmore v. Swift & Co.*.[72] In *Skidmore*, the Supreme Court held that courts can defer to agency interpretations based on a number of factors, including: (1) the thoroughness of the agency's consideration; (2) the validity of the agency's reasoning; and (3) the consistency of the agency's decision-making with earlier and later decisions.[73]

In three recent cases, *Christianson v. Harris County*,[74] *United States v. Mead Corp.*,[75] and *Barnhart v. Walton*,[76] the Supreme Court has revived the use of the *Skidmore* persuasiveness framework to address those less formal agency interpretations that do not enjoy the same kind of deference afforded more formal agency decisions, such as rulemaking and adjudications. The Government's briefs in *Tafas* use this framework as a "fall-back" position, contending that if the USPTO does not enjoy *Chevron* deference, then, the USPTO is still entitled to deference based on

67. 536 F.3d 1330 (Fed. Cir. 2008); Reply Brief for the Appellants, Tafas v. Dudas, No. 2008-1352 (Fed. Cir. filed Oct. 15, 2008).

68. 441 F.3d 1380 (Fed. Cir. 2006), *cert. denied*, 549 U.S. 1205 (2007).

69. 490 F.3d 1361 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 2080 (2008).

70. USPTO Appellant Brief, *supra* note 42, at 20-21.

71. *See* USPTO Appellant Brief, *supra* note 42, at 24 n.3 (arguing that statute constructions that are not entitled to *Chevron* deference are still entitled to *Skidmore* at a minimum); USPTO Summary Judgment Memo, *supra* note 41, at 20, n.11 (asserting that the agency would still qualify under *Skidmore*, and use the balancing factors).

72. 323 U.S. 134 (1944).

73. *Id.* at 140.

74. 529 U.S. 576 (2000). *Christianson* held that a Department of Labor opinion letter was not entitled to the *Skidmore* persuasiveness framework because it was not persuasive. *Id.*

75. 533 U.S. 218 (2001). *Mead* held that a customs ruling letter was entitled to respect under *Skidmore* to the extent that it was persuasive. *Id.* at 234-35.

76. 535 U.S. 212 (2002). The Court in *Barnhart* upheld a Social Security Administration regulation, even though it was based on a longstanding interpretation that had not originally been enacted by formal notice-and-comment rulemaking. *Id.* at 221-22. Although *Barnhart* referred to *Chevron* deference and not *Skidmore*, the Court cited *Mead* and implicitly employed the *Skidmore* persuasiveness framework. *Id.*

the factors outlined in *Skidmore*.[77]

Although governmental briefs treat this as a "fall-back" position, the premise of their argument has a particular valence in light of the Federal Circuit's decision in *Merck*. In the key passage of *Merck*, the Federal Circuit noted that:

> As we have previously held, the broadest of the PTO's rulemaking powers-35 U.S.C. § 6(a)-authorizes the Commissioner to promulgate regulations directed only to "the conduct of proceedings in the [PTO]"; it does NOT grant the Commissioner the authority to issue substantive rules. Because Congress has not vested the Commissioner with any general substantive rulemaking power, the "Final Determination" at issue in this case cannot possibly have the "force and effect of law." Thus, the rule of controlling deference set forth in *Chevron* does not apply. Such deference as we owe to the PTO's interpretive "Final Determination" regarding the interrelationship by the URAA and the Hatch-Waxman Act thus arises, not from the rule of *Chevron*, but solely from, *inter alia*, the thoroughness of its consideration and the validity of its reasoning, i.e., its basic power to persuade if lacking power to control.[78]

Two assumptions are immediately clear if the Federal Circuit's reasoning in *Merck* is unpacked. First, unlike the defendants' claim, *Merck* did not adopt the persuasiveness framework outlined in *Skidmore* because of the type of policy interpretation at stake, but rather because of the limited grant of authority outlined in Section 6 (the predecessor statute to Section 2).[79] Second, and just as importantly, unlike the *Tafas* plaintiffs and district court, the Federal Circuit did not assume that the text of Section 6 (now Section 2) immediately removes the ability of the USPTO to conduct "substantive" rulemaking whatsoever. Instead it subjects that "substantive" rulemaking to the lesser deference outlined in *Skidmore*.[80]

Recently in *Cooper Tech.*,[81] the Federal Circuit held that the USPTO did not have the substantive power to undertake rulemaking under Section 2,[82] but once again it did not clarify the ambiguity of *Merck* that led to the *Tafas* district court's strict presumption against *any* "substantive" rulemaking under Section 2.[83] Thus, the Federal Circuit can play an important role here in

77. *See supra* note 71 (reporting the USPTO's position that *Skidmore* applies where *Chevron* does not).

78. *Merck*, 80 F.3d at 1549-50 (citations omitted).

79. *Id.*

80. *Id.* After rejecting *Chevron* deference, *Merck* noted that the amount of deference owed was due to the rule's "basic power to persuade if lacking power to control." *Id.* (citing *Skidmore*, 323 U.S. at 140).

81. 536 F.3d at 1330.

82. *Id.* at 1336.

83. *Tafas*, 541 F. Supp. 2d at 811.

clarifying the ambiguities of *Merck* in its appellate review of *Tafas*, even if this might create a potential anomaly in the larger administrative regime to the extent that ordinarily rulemaking is not subject to *Chevron* deference. Such a rule ultimately makes sense, given the clear history and intent behind the grant of administrative power under Section 6 of the Patent Act (now Section 2).

Even if its arguments prove unavailing in the Federal Circuit, the governmental briefs in *Tafas* mark an important point in the USPTO's perception of itself. In *Tafas*, the USPTO attempted to re-frame itself as a "free" administrative actor, asserting its authority to behave as any other agency actor within a relevant field of expertise. Adopting this paradigm shows a significant change in how the USPTO perceives its institutional role.

For instance, the USPTO's briefs submitted ten years earlier, in *Dickinson v. Zurko*,[84] very much relied on the "exceptional" paradigm, contending that judicial review of fact-finding conducted by the Board of Patent Appeals and Interferences ("BPAI") should be reviewed under the more stringent "clearly erroneous" standard rather than the more deferential "substantial evidence" of Section 553 of the APA.[85] Acceptance of this paradigm within the relevant patent community has not been instantaneous. Indeed, the majority of the amicus briefs submitted in *Tafas* adamantly opposed this particular paradigm.[86] Of three submitted amicus briefs that did support this paradigm, they can be said, in some sense, to represent the "new" interest groups within the regulated patent community.[87]

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84. 527 U.S. 150 (1999).

85. Brief for the Respondents at *5-6, Dickinson v. Zurko, 527 U.S. 150 (1999) (No. 98-377), 1999 WL 21278, at *5-6; in *Dickerson*, the Supreme Court held that the APA's more deferential standard of judicial review applied to the USPTO, and not the more searching "clearly erroneous" standard that the Federal Circuit had been using. *Dickerson*, 527 U.S. at 155, 165.

86. *See* Justia.com Federal District Court Filings & Dockets, *Tafas v. Dudas*, (E.D. Va., filed Aug. 22, 2007) (No. 1:07-cv-846-JCC/TRJ) *available at* http://dockets.justia.com/docket/court-vaedce/case_no-1:2007cv00846/case_id-221151/ (listing nineteen amici curiae in support of the plaintiffs and opposed to the USPTO's new rules, as compared to three amici supporting the defendants).

87. *See* Brief for Amici Curiae Public Patent Foundation, Computer & Communications Industry Association, AARP, Consumer Federation of America, Essential Action, Foundation for Taxpayer and Consumer Rights, Initiative for Medicines, Access & Knowledge, Knowledge Ecology International, Prescription Access Litigation, Public Knowledge, Research on Innovation, and Software Freedom Law Center in Support of Defendants' Anticipated Motions for Summary Judgment at 1-2, *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008) (No. 1:07-cv-846-JCC-TRJ) (representing themselves as "Public Interest Amici" and supporting the USPTO's authority to issue the final rules at issue in *Tafas*); Brief of Amicus Curiae Micron

The linkage of activist groups with the Government's briefs in *Tafas* is an interesting development. Coupled with the ongoing congressional negotiations over the scope of patent reform, these submissions reflect the extent to which patent law is becoming the subject of intense interest group conflict at a wide-range of policy-making sites.[88]

3. *The District Court Decision: Adopting Patent Exceptionalism as the Norm*

The district court's holding in *Tafas* remained committed to patent exceptionalism. Judge Cacheris simply held that: "the Final Rules [were] substantive in nature and exceed the scope of the USPTO's rulemaking authority under 35 U.S.C. Section 2(b)(2)."[89] Once outside the scope of Section 2, the Final Rules were therefore enacted in excess of the USPTO's statutory jurisdiction and violated Section 706(2) of the APA.[90] The holding, however, resulted from the court's use of two key constraints that create a potentially distorted framework in which to address the paradigm challenge at the heart of *Tafas*.

Initially, the district court disavowed any reliance on a *Chevron* framework, stating that:

> [T]he Court emphasizes that its conclusion here renders it unnecessary to decide whether the USPTO's interpretation of the Patent Act should be given *Chevron* deference or whether the Final Rules run contrary to the Act's provisions. Instead, the Court need only explain why the Final Rules are substantive in nature and why they fall outside of Section 2(b)(2).[91]

This choice had a profound impact on the analytical structure of the opinion in that it leads to a cramped reading of *Merck*. *Merck* never stated that judicial review of substantive rulemaking was

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Technology, Inc., in Support of the Defendant's Anticipated Motion for Summary Judgment at 3-5, *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008) (No. 1:07-cv-846-JCC-TRJ) (arguing that the district court should let a co-equal branch of government "police its own jurisdiction and . . . manage its own docket"); Brief Amici Curiae of Intellectual Property, Administrative Law and Public Health Professors in Support of Defendants' Anticipated Motions for Summary Judgment at 1-5, *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008) (No. 1:07-cv-846-JCC-TRJ) (advocating *Chevron* deference to the USPTO's rules on the number of patent applications, which the amicus authors' view as procedural rather than substantive rulemaking).

88. *See, e.g.*, Donald S. Chisum, *Reforming Patent Law Reform*, 4 J. MARSHALL REV. INTELL. PROP. L. 336, 341-48 (2005) (analyzing the use of neutral principles in patent reform to counteract impact of interest groups on patent law reform).

89. *Tafas*, 541 F. Supp. 2d at 811.

90. *Id.*

91. *Id.* at 811 n.4.

entirely precluded. Rather, *Merck* declared that such substantive interpretations issued by the USPTO would be subject to a *Skidmore* persuasiveness framework.[92]

Thus *Merck* does not stand for the proposition that substantive rulemaking can never be conducted by the USPTO. The *Tafas* district court's misreading of *Merck* within a standard administrative framework has the unfortunate consequence of heightening *Merck*'s subtle use of the "substantive/procedural" distinction—as a way to define the ultimate persuasiveness of a given agency decision-making—to the strict presumption that the USPTO cannot undertake any substantive rulemaking at all. This strict presumption, furthermore, will place courts in the difficult position of determining whether the disputed agency action is a procedural or substantive one. Such an inquiry has often been called "one of the most difficult decisions in administrative law" and one on which neither Congress nor the courts have provided much useful guidance.[93] Indeed, the Federal Circuit can and should use *Tafas* to reject this strict presumption.

Additionally, the district court's insistence on the USPTO distinctiveness is reinforced by its constrained textual analysis of Section 2. In particular, the *Tafas* court stressed the presence of the term "and," indicating that the text of Section 2(b)(2)(A) and (B) need to be read together, to require that the USPTO undertake notice and comment rulemakings under Section 553 of the APA when seeking to determine procedures for agency proceedings.[94] Thomas Fields has subjected this particular interpretation to a withering criticism, noting that the court's reading would require that the USPTO conduct notice and comment rulemaking for its procedural rules, when traditionally the text of Section 553(b) itself exempts such rules from review under the APA.[95] Like the

92. *Merck*, 80 F.3d at 1543; *see supra* notes 77-80 and accompanying text (discussing *Merck's* rejection of *Chevron* deference when reviewing a USPTO final determination, but implicit adoption of *Skidmore* persuasiveness).

93. WILLIAM K. FOX, UNDERSTANDING ADMINISTRATIVE LAW 186 (5th ed. 2008). *See generally* Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705 (2007) (outlining scholarly consensus on difficulty of applying substantive distinctions between substantive and procedural rules). As Herbert Wamsley noted in 1982, as this same debate occurred around the USPTO's use of rulemaking powers under Section 6 (Section 2's predecessor), "[a]ny rule, however, even a purely advisory one, is "substantive" if it deals with the substantive requirements of the laws administered by the agency, in contrast to the agency's rules of practice or other procedural requirements." Herbert C. Wamsley, *The Rulemaking Power of the Commissioner of Patents and Trademarks (Part 2)*, 64 J. PAT. OFF. SOC'Y 539, 542 (1982).

94. *Merck*, 541 F. Supp. 2d at 812.

95. Thomas G. Field, Jr., *Tafas v. Dudas: Elephants in Mouseholes*, IPFrontline, Apr. 16, 2008, http://www.ipfrontline.com/depts/article.asp ?id=18491&deptid=4.

court's reading of *Merck*, its reading of the textual elements of Section 2 enshrines a patent exceptionalism even where basic elements of the law do not sustain this premise.

In many ways, despite its logical flaws, the district court's decision reflects the difficulty of the choice it faced. The strict presumption that the USPTO cannot conduct substantive rulemaking at all might be a necessary alternative to the Government's insistence on *Chevron* deference to rulemaking, even where it was conducted with potentially significant flaws.[96] But there is another option. The alternative to, of course, is the Federal Circuit's useful guidance in *Merck*. So long as Section 2 contains a limited grant of power, then the *Skidmore* persuasiveness framework should apply to notice and comment rulemaking on substantive issue.[97]

Using the *Skidmore* framework would have three significant benefits. First, it has the benefit of simplicity insofar as it does not depend on Congress to revise Section 2 (a task that has proven to be particularly difficult within the context of current patent reform). Second, use of the framework allows significant judicial review of the USPTO's interpretative decision-making (a choice that is potentially not allowed under the district court's strict presumption against substantive rulemaking). Finally, the Federal Circuit has significant experience in applying the *Skidmore* persuasiveness framework[98] and indeed, has thoroughly

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96. At least one amicus brief focused on the significant flaws associated with the USPTO's conduct during the rulemaking process. Memorandum of Amicus Curiae Ron D. Katznelson in Support of Plaintiffs Motions for Summary Judgment at 1-7, *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008) (No. 1:07-cv-846-JCC-TRJ), 2007 WL 5061369 at *1-7.

97. This is not an ideal situation since the court would still engage in the difficult determination whether the USPTO engaged in substantive or procedural rulemaking. *See supra* note 93 (explaining that resolving this question is a particularly difficult choice in administrative law). The district court's ruling, however, would create a significant disincentive to actually conduct rulemakings on any issue if no deference is accorded to the USPTO's decision-making at all. The *Skidmore* framework also benefits from having been examined within the academic literature. *See, e.g.*, Kristin E. Hickman & Matthew D. Krueger, *In Search of the Modern Skidmore Standard*, 107 COLUM. L. REV. 1235, 1259-71 (2007) (providing empirical evidence of the use of the *Skidmore* persuasiveness framework).

98. The Federal Circuit has applied the *Skidmore* persuasiveness framework within the context of at least one patent case. *See* Bayer AG v. Carlsbad Tech., Inc., 298 F.3d 1377, 1381 (Fed. Cir. 2002) (discussing the *Skidmore* persuasiveness factors). The Federal Circuit has used the *Skidmore* framework to deferentially analyze agency interpretative decision-making in a variety of contexts. *See, e.g.*, MetChem, Inc., v. United States, 513 F.3d 1342, 1345 (Fed. Cir. 2008) (applying *Skidmore* framework to give some deference to customs classifications ruling); Caribbean Ispat Ltd. v. United States, 450 F.3d 1336, 1340 (Fed. Cir. 2006) (denying *Skidmore* framework deference to

explored the contours of its *Skidmore* approach in two major cases, *Mead*[99] and *Cathedral Candle Co. v. United States International Trade Commission.*[100]

In *Mead*, on remand from the Supreme Court, the Federal Circuit considered whether to defer to the International Trade Commission's ("ITC") classification ruling that imported day planners should be classified as bound diaries.[101] In rejecting deference to that classification ruling, the Federal Circuit emphasized that in addition to the *Skidmore* factors, the court would consider the relative expertise of the Commission in undertaking its classification.[102]

In *Cathedral Candle*, the Federal Circuit examined whether to defer to the ITC's interpretation that a disclosure provision of the now repealed Continued Dumping and Subsidy Offset Act of 2000 (commonly called the Byrd Amendment)[103] did not override a confidentiality provision of the Tariff Act of 1930.[104] The majority opinion in *Cathedral Candle*, authored by Circuit Judge Bryson, is a thoughtful examination of the *Skidmore* persuasiveness framework. In particular, in analyzing the *Skidmore* persuasiveness framework, Judge Bryson stated that use of *Skidmore* did not mean that the Federal Circuit could not conduct an independent review of the statutory provision at issue, but rather had to:

> [D]efer to an agency interpretation of the statute that it administers if the agency has conducted a careful analysis of the statutory issue, if the agency's position has been consistent and reflects agency-wide policy, and if the agency's position constitutes a reasonable conclusion as to the proper construction of the statute, even if we might not have adopted that construction without the benefit of the agency's analysis.[105]

The Federal Circuit's approach in *Mead* and *Cathedral Candle* usefully articulates a way to approach the question of "patent exceptionalism" in so far as it recognizes that Section 2

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an argument advanced in litigation by the International Trade Commission); Eldredge v. Dept. of Interior, 451 F.3d 1337, 1342-43 (Fed. Cir. 2006) (rejecting *Skidmore* framework deference to advisory opinions); Pacific Gas & Elec. Co. v. United States, 417 F.3d 1375, 1385 (Fed. Cir. 2005) (according no *Skidmore* framework deference to classifications in internal IRS documents).

99. 283 F.3d at 1346.

100. 400 F.3d 1352, 1365-68 (Fed. Cir. 2005).

101. *Mead*, 283 F.3d at 1344.

102. 283 F.3d at 1346.

103. Pub. L. No. 106-387, 114 Stat. 1549, 1549A-72 to -75 (2000) (codified as amended at 19 U.S.C.A. § 1675(c) (West 2009)) (repealed 2006).

104. 19 U.S.C.A. § 1677f (West 2009); *Cathedral Candle*, 400 F.3d at 1365-68.

105. 400 F.3d at 1366.

accords a narrow scope for the USPTO to conduct rulemaking but still allows review for of its interpretative choices under a rigorous framework that adheres to standard principles of administrative law. Additionally, *Mead* and *Cathedral Candle* can usefully ground *Merck* as a case in which standard administrative law principles are at stake. This undermines a key consequence of patent exceptionalism in which other important sources of administrative interpretations by the Federal Circuit are not fully assimilated into an overall patent jurisprudence.[106]

It appears anomalous that a rulemaking, conducted through the notice-and-comment process, would not be given *Chevron* deference. *Chevron* deference, while granting a strong preference to notice-and-comment rulemaking, does not automatically apply to *every* rulemaking. The majority opinion in *Mead,* authored by Justice Souter, noted that while notice-and-comment was a "good indicator" that Congress intended to accord deference, the primary indicator of *Chevron* deference is whether Congress intended the rules to have what he terms the "force of law." [107]

Amy Wildmuth noted that Justice Souter's opinion "leaves the door open for Congress to override this [*Chevron*] presumption by providing in clear terms that, although it is requiring the agency to engage in, for example, notice-and-comment [rulemaking], the rules adopted by the agency are not to have the force of law."[108]

Indeed, the Federal Circuit had previously applied *Skidmore* deference in a circumstance where the agency had engaged in notice-and-comment rulemaking. In *Rubie's Costume Co. v. United States*,[109] the Federal Circuit examined whether a tariff classification ruling published pursuant to notice-and-comment rule making could be accorded deference under *Chevron*.[110] The Federal Circuit concluded that all custom classification rulings—including those conducted through notice-and-comment rulemaking—could only be accorded *Skidmore* deference.[111]

106. In 1995, Craig Nard noted that the Federal Circuit itself has often adopted a much more consistent approach to administrative law within its review of the ITC's cases. Nard, *supra* note 3, at 1432.

107. *Mead*, 533 U.S. at 231-32 n.11.

108. Amy J. Wildermuth, *Solving the Puzzle of Mead and Christensen: What Would Justice Stevens Do?*, 74 FORDHAM L. REV. 1877, 1885 (2006).

109. 337 F.3d 1350 (Fed. Cir. 2003).

110. *Id.* at 1355.

111. *Id.* Despite the fact that "the classification ruling before the Supreme Court in Mead was not . . . subject to a deliberative notice-and-comment rulemaking process, we read the Court's holding as applying to all Customs classification rulings." *Id.* (citing Heartland By-Prods., Inc. v. United States, 264 F.3d 1126, 1135 (Fed. Cir. 2001). *See Mead*, 533 U.S. at 234 (concluding that import classification rulings are not entitled to *Chevron* deference). After rejecting *Chevron* deference, however, the court did approve of using the *Skidmore* framework to accord some deference to persuasive classifications of

Arguably, the textual ambiguity of Section 2 creates a circumstance where a notice-and-comment rulemaking may not be accorded judicial deference. Ultimately, *Skidmore* deference is the appropriate framework for courts to employ when addressing the consequences of the potentially ambiguous grant of authority under Section 2.

B. Why Patent Exceptionalism?

The paradigm of patent exceptionalism, as demonstrated by *Tafas*, is one with long-standing power within the context of patent law given that the inclusion of Section 6 in the Patent Act has always been seen to be a relatively straightforward choice. Congress included this language in the Patent Act of 1870 and the drafters of the Patent Act of 1952 simply repeated the language of the previous statute.[112] Thus, the intent of the drafters of the 1952 Patent Act just reflected the already pre-existing understanding that the USPTO would not exercise a full rulemaking ability. The text of Section 6, though, was in many ways an anachronism. Indeed, the inclusion of Section 6 in the 1952 Patent Act, was a choice that deliberately sought to minimize the impact of the APA on the patent regime. Re-casting the historical context under which Section 6 was passed heightens awareness that patent exceptionalism did not emerge from the basic nature of the administrative tasks undertaken by the USPTO. In its entirety, Section 6 of the Patent Act of 1952 stated that:

> The Commissioner, under the direction of the Secretary of Commerce, shall superintend or perform all duties required by law respecting the granting and issuing of patents and the registration of trademarks; and he shall have charge of property belonging to the Patent Office. He may, subject to the approval of the Secretary of Commerce, establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent Office.[113]

Section 6 of the Patent Act combined two previous statutory provisions together.[114] The second sentence of Section 6 was derived from Section 19 of the Patent Act of 1870.[115] Section 19 stated "[t]hat the commissioner, subject to the approval of the Secretary of the Interior, may from time to time establish rules

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imports. *Rubie's Costume*, 337 F.3d at 1355.

112. Herbert C. Wamsley, *The Rulemaking Power of the Commissioner of Patents and Trademarks (Part 1)*, 64 J. PAT. OFF. SOC'Y 490, 493-97 (1982).

113. Patent Act of 1952, Pub. L. No. 593-950, § 6, 66 Stat. 792, 793 (1952) (current version at 35 U.S.C.A. § 2 (West 2009)).

114. SEN. REP. NO. 82-1979, at 2405 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2405.

115. Patent Act of 1870, ch. 230, § 19, 16 Stat. 198, 200 (1870) (current version at 35 U.S.C.A. § 2.

and regulations, not inconsistent with law, for the conduct of the proceedings in the patent office."[116] As Herbert Wamsley noted in his definitive account of the legislative history of Section 6, "there is no evidence any change in substance was intended in the provision that became Section 6 of Title 35 of the United States Code granting the Commissioner rulemaking power."[117] The text of Section 6, then, is remarkable in its adherence to continuity with earlier law.

This text, however, when viewed in its proper historical context, should be seen as a radical choice. Historical treatments of the patent regime have tended to focus on the development of the patent regime in the eighteenth and nineteenth centuries. Recently, however, these treatments have begun to focus on how patent law evolved in the twentieth century. For instance, Steven Wilf has examined how controversy over the movement from individual inventors to a more institutional model of scientific development has impacted patent law.[118]

An equally important development for patent law, and in particular, the drafting of Section 6, was the ongoing controversy that surrounded the expansion of the administrative state in 1930s, and the subsequent use of administrative law to control that expansion. Recent scholarship has stressed successive attempts in Congress, beginning in 1933, to pass an administrative law bill that would have constrained the powers of federal agencies, which had experienced an explosive growth as a result of the New Deal regime.[119]

From 1929 to 1946, Congress attempted to pass at least four major bills that sought comprehensive administrative reform. First, the Norris Bill (1929), sought to establish a Court of Administrative Justice, which would have consolidated all of the administrative courts (including the Court of Customs and Patent Appeals) into one pre-eminent court.[120] Second, the Logan-Cellar Bill (1936), sought to impose additional adjudicatory procedures on

116. *Id.*

117. Wamsley, *supra* note 112, at 497.

118. Steven Wilf, *The Making of the Post-War Paradigm in American Intellectual Property Law*, 31 COLUM. J. L. & ARTS 139, 198-03 (2008).

119. For a comprehensive account of the passage of the Administrative Procedure Act, *see* George B. Shepherd, *Fierce Compromise: The Administrative Procedure Act Emerges from New Deal Politics*, 90 NW. U. L. REV. 1557, 1561-78 (1996) (outlining the historical circumstances for understanding the passage of the APA); *see also* Reuel E. Schiller, *The Era of Deference: Courts, Expertise and the Emergence of New Deal Administrative Law*, 106 MICH. L. REV. 399, 405 (2007) (exploring the impact of the New Deal on administrative law).

120. S. 5154, 70th Cong., (2d Sess. 1929); *see also* Shepherd, *supra* note 119, at 566-68 (recounting the legislative history of the never enacted Norris Bill).

agency behavior.[121] Third, the Walter-Logan Bill (1939), the most sweeping of the suggested bills, which, among other items, sought to formalize rulemaking to provide for inter-department review of decisions in all agencies, and to provide for review by federal appellate courts of all final decisions of administrative agencies.[122] Fourth, the McCarran-Sumners Bill (1944), which ultimately led to the passage of the APA and included many of its major provisions, such as the substantive publication requirements, formal and informal rulemakings, and full hearings for adjudications.[123]

Of these bills, the Walter-Logan Bill was the most controversial because it exempted many agencies, including the USPTO from its purview.[124] The attempted passage of the Walter-Logan Bill was accompanied by a vociferous debate over whether the agencies of federal government should enjoy the significant increase in their powers that occurred during the New Deal.[125] Such exemptions continued in subsequent drafts of administrative law bills. For instance, an early predecessor of the eventual McCarran-Sumners Bill exempted the USPTO from formalized adjudicatory proceedings.[126]

The opposition to the any major changes in the patent administrative regime during the New Deal Era is striking and consistent.[127] Both the regulated community as well as

121. S. 3787, 74th Cong., (2d Sess. 1936); *see also* Shepherd, *supra* note 119, at 1578-79 (reviewing the legislative history of the Logan-Cellar Bill that died in committee).

122. S. 915, 76th Cong., (1st Sess. 1940); *see also* Shepherd, *supra* note 119, at 1593-28 (exploring the legislative history of the Walter-Logan Bill that Congress enacted but President Roosevelt vetoed).

123. S. 2030, 78th Cong., (2d Sess. 1944); H.R. 5081, 78th Cong., (2d Sess. 1944); *see also* Shepherd, *supra* note 119, at 1649-52 (examining the legislative history of the McCarran-Sumners Bill that would become the APA).

124. S. 915 at § 7; *see also* Shepherd, *supra* note 119, at 1618 (listing the Patent Office as one of the many federal agencies that would have been exempt from the Walter-Logan Bill).

125. *Compare* O.R. McGuire, *The American Bar Association's Administrative Law Bill*, 1 LA L. REV. 550, 556 (1939) (discussing the ABA's support for a bill similar to, but with significant difference from, the Walter-Logan Bill), *with* Alfred Jaretzki, Jr., *The Administrative Law Bill: Unsound and Unworkable*, 2 LA L. REV. 294, 294-300 (1940) (opposing ABA's bill because a uniformed procedure was believed to be unworkable in this context).

126. H.R. 3464, 77th Cong. § 708(c) (1st Sess. 1941); *see also* Shepherd, *supra* note 119, at 1636-38 (remarking that unlike prior legislation that exempted a number of federal agencies, only the USPTO office sought an exemption under this bill).

127. Academic commentators also remarked upon this resistance. *See* William Redin Woodward, *A Reconsideration of the Patent System as a Problem of Administrative Law*, 55 HARV. L. REV. 950, 951 (1940) (arguing that because the patent system came before administrative law principles

administrators expressed consistent opposition to inclusion in the administrative regime. From 1931 until 1941, the Section of Patent, Trademark and Copyright Law of the American Bar Association ("the Section") consistently opposed any major changes to the patent regime, including:

- In 1936, the Section opposed the consolidated Administrative Court;[128]
- In 1937, the Section objected to the inability to sue the Tennessee Valley Authority for patent infringement,[129] opposed a consolidated Administrative Court,[130] and convinced the Section of Administrative Law to exclude the Patent Act from its suggested Administrative Law Bill (which ultimately became the Walter-Logan Bill);[131]
- In 1938, the Section reported continued lobbying to exclude the Patent Act from the suggested Walter-Logan Bill;[132]
- In 1939, the Section reported continued lobbying to exclude the Patent Act from the suggested Walter-Logan Bill;[133]
- In 1940, the Section opposed the consolidated Administrative Court.[134]

The Section began to lessen its opposition, beginning in 1942. In particular, the Section decided to follow the broader ABA position on comprehensive administrative law reform, which had expanded to covering all federal agencies.[135] The Section, however, continued to object to two key provisions of administrative law

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developed, patents should not be analyzed through an administrative law regime). Notably, Mr. Redin focused his attention on the problem of judicial review of patents in private litigation. *Id.* at 955-66.

128. 1936 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 10.

129. 1937 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 10.

130. *Id.* at 13-14.

131. *Id.* at 23.

132. 1938 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 6.

133. 1939 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 17-20.

134. 1940 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 12.

135. *See* 1942 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 22 (reporting that the Section resolved to "take no action whatsoever" against proposed legislation H.R. 3464, 4238; S. 674, 675 and 918, other than two objections); *infra* note 136 and accompanying text (discussing the Section's two objections to the proposed administrative act legislation).

The Section described the proposed legislation as being the result collaboration between the ABA and the Attorney General. 1942 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 22; *see also* Shepherd, *supra* note 119, at 1647 (describing the ABA's transformation from adamant opposition to compromise in the period 1941-45, regarding passage of an administrative act). The proposed legislation that the Section no longer opposed did include all federal agencies, unlike previous versions which had excepted the USPTO and other departments. *Id.* at 1649.

reforms. In particular, the Section objected to the provisions of the suggested reform that would alter the existing rules for admissions to the USPTO (by granting any individual the ability to practice before the Office), as well those portions that "would lend statutory force to Patent Office rules not arising in statute."[136] In 1943, the Section continued to support the ABA's suggested draft but also continued to raise objections to proposed administrative rules of practice that would allow any lawyer to practice before the USPTO and exclude non-lawyers from practice before the USPTO.[137] By 1944, the Section, commenting on the Walter-McCarran Bill, generally approved of the Bill, but noted continuing objections with: (1) the use of notice and comment rulemaking to promulgate substantive rules "not based on statute"; (2) the provisions of the Bill that sought to replace Board of Appeals and the Board of Interference Examiners with an independent set of administrative commissioners; and (3) the admission of attorneys without technical or scientific expertise.[138]

The regulators themselves also expressed considerable ambivalence about inclusion into a normalized administrative regime. For example, in 1941, the then Assistant Commissioner Conder C. Henry expressed significant concerns over the inclusion of rule making in a proposed Senate Bill. He objected to the inclusion of broad grant of rulemaking power because it "is our opinion that a rule can be promulgated to fit the average situation but not the special facts of a particular case, and the facts of practically every application for patent are particular."[139] Likewise, he objected to a section that would have prohibited agencies from relying on "unpublished rules, instructions or statements" because such a provision:

> [S]eeks to attain stability and rigidity in, administrative adjudications; that it seeks that complete and absolute legal certainty which is sought to be attained by fixed, wholly inflexible, rules authoritatively prescribed in advance to cover every possible circumstance and applied to intangibles (such as inventions) . . . with machinelike precision. This idea is based upon the age-old longing for permanency, regularity, ultimate security, and sameness

136. 1942 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 22; *see also* 1941 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 13 (referring to a debate within the Section on whether only attorneys would be allowed to practice before the USPTO).

137. 1943 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 14.

138. 1944 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 16-18.

139. *Administrative Procedure: Hearing on S. 674, S. 675, and S. 918 Before a Subcomm. of the S. Comm. on the Judiciary*, 77th Cong. 612-13 (1941) (statement of Conder C. Henry, Assistant Comm'r on Patents).

in human relationships; and it is fantasy.[140]

After passage of the APA itself, Caspar Ooms, Commissioner of the Patent Office, stated in response to the question why he believed "this Act was not intended to apply to the Patent Office:"

> That has been expressed at various times in earlier drafts of the legislation. As the Act is now drawn it does apply to the Patent Office in the few respects I have enumerated. That is, we are not expressly excluded as we were in one of the earlier drafts. But all of the studies shook us off. They took one look at the Patent Office and said that they did not want to get into there, that it was too complex. It is unfortunate, because if one studies that very interesting development of review beyond the Patent Office, of Patent Office adjudications, starting back in 1836 and sees it changes from year to year you have some appreciation of the fact that the problem of review of administrative decisions is not new.[141]

Notably, in this passage, Commissioner Ooms referred to an article written by P.J. Federico[142]—who would later become one of the primary drafters of the Patent Act of 1952—outlining the historical practices associated with adjudication before the USPTO.[143] In a narrower respect as to rulemaking, Commissioner Ooms noted that he believed that the APA did not apply to most of the rulemakings undertaken by the USPTO, since "t]he statute does not expressly require it with respect to the Patent Office because of the very broad exemptions, inasmuch as most of our rules are procedural or formulations of policy expressed in the statute."[144] This view, expressed by Commissioner Ooms, is mirrored by the text of Section 6 of the 1952 Patent Act.

Section 6's reliance on the textual language from the Patent Act of 1870, then, is not unintentional. In significant ways, Section 6 seeks to preserve and re-state the role of the USPTO as independent from the type of procedural safeguards associated with the modern administrative state. Thus, the peculiar relationship that the USPTO has had with the APA is due, in some significant sense, to this early skepticism—if not outright resistance—to the usefulness of administrative law to the patent regime. This, of course, has had significant consequences.

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140. *Id.* at 613.

141. Caspar W. Ooms, *The United States Patent Office and the Administrative Procedure Act in* THE FEDERAL ADMINISTRATIVE PROCEDURE ACT AND THE ADMINISTRATIVE AGENCIES 253, 276-77 (George Warren ed., 1947).

142. *Id.* at 277.

143. *See generally* P.J. Frederico, *Evolution of Patent Office Appeals*, 22 J. PAT. OFF. SOC'Y 838 (1940) (tracing the history of appeals from USPTO decisions).

144. Ooms, *supra* note 141, at 275.

First, a whole set of ancillary administrative law doctrines, such as the question of selecting what is the appropriate standard for judicial review under the APA, or the question of standing for third party interests, has not been substantively applied to the Patent Act. Moreover, it has created a situation where participation in the patent regime is significantly under-theorized. In many respects, the patent regime has not always successfully incorporated theories of participation, whether it be interest group pluralism or participatory and deliberative democratic theory, and thus the type of constituency conflict at the heart of *Tafas* has not always been successfully channeled within the patent administrative regime.[145]

III. A PRINCIPLED APPROACH TO PATENT ADMINISTRATIVE LAW

A new approach is needed if *Tafas* represents a new movement towards rejecting patent exceptionalism. The Government's briefs in *Tafas* posit a full assimilation into the larger administrative regime, with the interpretative decision-making of the USPTO offered a full-fledged *Chevron* deference. Full assimilation into the administrative regime, however, might not be possible given the unique qualities of patent law. Principle one—that USPTO agency action must be reconciled with standard administrative doctrine—attempts to articulate the ways in which the unique nature of patent procedures can be accommodated with administrative law. Principle two—that reconciliation must involve the patent civil society—is a necessary corollary to the first because USPTO reconciliation to the administrative state would increase opportunities for sustained third party challenges to administrative action.

A. Principle One: USPTO Agency Action Must Be Reconciled With Standard Administrative Doctrine

Reconciling the USPTO with the wider administrative state involves two choices: full reconciliation with the administrative state, or a more partial reconciliation with the administrative state. In the end, if it does anything useful, *Tafas* makes explicit the growing urge to assimilate administrative law within patent law. Indeed, *Tafas* should indicate the end of the culture of patent

145. *See generally* Reuel E. Schiller, *Rulemaking's Promise: Administrative Law and Legal Culture in the 1960s and 1970s*, 53 ADMIN. L. REV. 1139 (2001) (outlining the development of an interest group pluralism in post war United States, and the clash between increased administrative rulemaking and heightened judicial review of such rulemaking); Kali Murray, *Rules for Radicals: A "Politics" of Patent Law*, 14 J. INTELL. PROP. L. 63 (2006), (outlining the different types of political models that can inform patent reform models).

exceptionalism within the context of administrative law. Full assimilation is a necessary development in patent law for three reasons.

First, the scope of administrative action undertaken by the USPTO has developed in considerable ways since the enactment of Section 6 in 1952. The clear text of the Patent Act itself has served to obscure other changes in the administrative regime. This is an achievement that stands in stark contrast to the Copyright Act, which has become a somewhat unwieldy conglomerate of various provision engrafted upon the original text.[146] This supposed serene consistency of the Patent Act has done much to mask a significant underlying dynamism in the patent administrative regime. Initially, the role of the USPTO underwent significant administrative expansion with subsequent amendments to the Patent Act of 1952, including providing different types of regulatory procedures, such as: (1) re-examination;[147] (2) voluntary arbitration;[148] (3) patent restoration extension;[149] and (4) optional inter partes re-examination proceedings.[150] Other amendments to the 1952 Act also expanded the USPTO's role in advising compliance with international treaties.[151]

146. *See generally* David Nimmer, *Codifying Copyright Comprehensibly*, 51 UCLA L. REV. 1233 (2004) (outlining the failure to maintain a concise copyright statute after the passage of the Copyright Act of 1976).

147. *See* An Act to amend the patent and trademark laws, Pub. L. No. 96—517, 94 Stat. 3015, 3015-17 (1980) (codified as amended at 35 U.S.C.A. § 302-07 (West 2009)) (outlining changes to re-examination procedures).

148. *See* An Act to authorize appropriations to the Patent and Trademark Office in the Department of Commerce, and for other purposes, Pub. L. No. 97-247, 96 Stat. 317, 322 (1982) (codified as amended at 35 U.S.C.A. § 294 (West 2009)) (adding voluntary arbitration procedures for the resolution of patent disputes).

149. *See* An Act to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes, Pub. L. No. 98—417, 98 Stat. 1585, 1598-02 (1984) (codified as amended at 35 U.S.C.A. § 156 (West 2009)) (adding new procedure for patent extension).

150. *See* Optional Inter Partes Reexamination Act of 1999, Pub. L. No. 106-113, 113 Stat. 1501, 1501A-567 to -70 (1999) (codified as amended at 35 U.S.C.A. § 311-18 (West 2009)) (enacting procedures for the optional use of inter partes re-examination proceedings); *See generally* Edward C. Walterscheid & Kenneth L. Cage, *Jurisdiction of the Patent and Trademark Office to Consider the Validity of Issued Patents*, 61 J. PAT. OFF. SOC'Y 444 (1979) (outlining the changes in patent law that allowed the USPTO to consider regulation of patents within the post-issuance context).

151. *See* An Act to amend section 6 of title 35, United States Code, "Patents," to authorize domestic and international studies and programs relating to patents and trademarks, Pub. L. No. 92-132, 85 Stat. 364, 364 (1971) (codified as amended at 35 U.S.C.A. § 6 (West 2009)) (current version at 35 U.S.C.A. §

Such changes are significant in that they have expanded the number of tasks that constitute the administrative authority of the USPTO, a change that is recognized in the text of the newly constituted Section 2. Section 2 is qualitatively more expansive than Section 6. In particular, the text recognizes the role of the USPTO in facilitating and processing the applications and serving in an advisory capacity on international treaties and cooperation.[152] A real risk exists in not understanding the contours of this new regime, and the one difference between *Tafas* and *Merck* may lie (correctly) in understanding the new textual scope of Section 2.

Second, the contours of the patent regime have expanded considerably to allow a number of other administrative actors such as the ITC, the Food and Drug Administration ("FDA"), the Federal Trade Commission ("FTC"), and the Department of Justice ("DOJ"), to substantively regulate the post-issuance grant of a patent.[153] These agencies are subject to the broader administrative law framework and in fact, as previously discussed, the Federal Circuit itself has developed a more consistent approach in its administrative law jurisprudence within the context of the ITC.[154] This standard is in stark contrast with the Federal Circuit's jurisprudence in the context of patent law, which has often bore little resemblance to more standardized administrative review.[155]

Third, the APA requires that a government agency engage in a substantive, transparent process that allows interested citizens the ability to challenge agency refusal to fully account for relevant factors in agency decision-making.[156] These requirements are in

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2(b)(8)-(13)) (expanding USPTO's advisory capacity over ensuring compliance with international treaties); An Act to carry into effect certain provisions of the Patent Cooperation Treaty, and for other purposes, Pub. L. No. 94-131, 89 Stat. 685, 685-92 (1975) (codified as amended in scattered sections of 35 U.S.C.A.) (increasing USPTO's advisory capacity to ensure compliance with the Patent Cooperation Treaty ("PCT")); An Act to amend the patent laws implementing the Patent Cooperation Treaty, Pub. L. No. 99-616, 100 Stat. 3485, 3485-87 (1986) (codified as amended in scattered sections of 35 U.S.C.A.) (enlarging USPTO's advisory capacity to ensure compliance with the PCT).

152. *See* 35 U.S.C.A. § 2(b)(2)(C) (stating that the USPTO ensures processing of the patent applications); 35 U.S.C.A. § 2(B)(12) (outlining the USPTO's advisory capacity in international relations).

153. *See generally* Kali Murray, *The Cooperation of Many Minds: Domestic Patent Reform in an Heterogeneous Regime*, 48 IDEA 289 (2008) (outlining the roles of federal agencies other than the USPTO in the regulation of patents).

154. *See supra* notes 99-106 and accompanying text (reviewing the Federal Circuit's more deferential treatment of the ITC's rulemaking).

155. *See* Benjamin & Rai, *supra* note 3, at 318-20 (outlining the level of review that the Federal Circuit should accord the actions of the USPTO).

156. *See., e.g.*, Jason J. Czarneski, *Revisiting the Tense Relationship Between*

accord with another trend in patent law: transparency mechanisms have substantially increased in current patent law.

This trend toward more transparency began with the implementation of the eighteen-month publication requirement under Section 122.[157] This transparency in publication of a patent application has been heightened by electronic mechanisms such as the Patent Application Information Retrieval ("PAIR") system that allows for a substantive review of the entire prosecution history of a patent application.[158] These projects arise in no significant part due to a grant of authority in Section 122, which grants the USPTO final and unreviewable authority to release or not release information concerning a published patent application.[159]

Indeed, transparency mechanisms have been deepened significantly by experiments such as the Peer to Patent Project, which allowed designated third parties to comment on designated prior art during the course of a limited number of patent applications.[160] These collected transparency requirements move the USPTO towards a broader role than that initially contemplated by the 1952 grant of authority in Section 6.

It is far more likely, however, that patent law would only be gradually reconciled with administrative law. Significant challenges await full assimilation. First, the policy-making forms outlined by the Patent Act do not usefully correspond with those outlined in the APA. Section 551 of the APA outlines three types of agency proceedings (rulemakings, adjudication, and licensing) and five types of agency actions (rules, orders, licenses, sanctions and relief).[161] The Patent Act outlines a range of administrative actions that do not neatly fit in these enumerated categories.

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the U.S. Supreme Court, Administrative Procedure, and the National Environmental Policy Act, 25 STAN. ENVTL. L.J. 3, 13-16 (2006) (outlining the usefulness of the APA in providing more stringent review of environmental decision-making).

157. *See* 35 U.S.C.A. § 122(b) (outlining the publication requirement for patent application). Four exceptions exist to this publication requirement, for: (1) an application that is no longer pending; (2) an application is subject to a secrecy order; (3) an application is a provisional application; (4) an application that is for a design patent application. *Id.* § 122(b)(2)(A).

158. *See* USTPO Public Pair Database, http://portal.uspto.gov/external/portal/pair (last visited Feb. 17, 2009) (allowing for online patent searches at the USPTO's website).

159. 35 U.S.C.A § 122(b).

160. *See* The Peer to Patent Project: Community Patent Review, http://www.peertopatent.org/ (last visited Feb. 21, 2009) (reporting that with the consent of the inventor, the patent examination is opened online to enable the public to submit prior art and commentary on pending patent applications).

161. *See* 5 U.S.C.A. § 551(4)-(13) (West 2009) (defining the types of agency actions and proceedings that are covered by the APA).

Beyond the conduct of the rulemaking at stake in *Tafas*, the USPTO is responsible for administering the following categories of agency decision-making under the Patent Act: (1) the examination of patent application by patent examiners;[162] (2) the conduct of interference between two patent applicants;[163] (3) the review of examination and interference proceedings before the BPAI;[164] (4) the ability to restore patent term under the Hatch-Waxman Act;[165] (5) the ability to conduct a review of reissued patents,[166] terminal disclaimers,[167] and certificate of corrections issued for agency and patentee mistakes;[168] and (6) the conduct of ex parte re-examination[169] and optional inter partes proceedings.[170]

The process of reconciling the Patent Act's enumerated policy-making forms with the review standards of the APA has been an awkward one. For instance, in *In re Gartside*, the Federal Circuit confronted how to classify appeals of examiner decisions and interference proceedings before the USPTO.[171] The Court ultimately determined that the decisions of the BPAI were to be reviewed as an "agency hearing" because, unlike other formalized adjudicatory proceedings, decisions of the BPAI were followed by a subsequent trial de novo at the district court.[172] This determination had the direct consequence of allowing the Federal Circuit to review BPAI decisions under what it termed the more stringent "substantial evidence" rather than the more deferential "arbitrary and capricious" standard of APA Section 706 (2)(A) that applies to broader categories of agency action.[173]

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162. *See* 35 U.S.C.A. § 131 (West 2009) (outlining the authority of the Director to conduct examination of patents).

163. *See* 35 U.S.C.A. § 135 (West 2009) (proscribing the conduct of interference proceedings).

164. *See* 35 U.S.C.A. § 6 (describing the procedures of BPAI); 35 U.S.C.A. § 134 (West 2009) (stating the right of review before the BPAI).

165. *See* 35 U.S.C.A. § 155-155A (West 2009) (explaining the authority of the USPTO in restoring the patent terms of pharmaceutical patents under regulatory review of the FDA).

166. *See* 35 U.S.C.A. § 251 (West 2009) (outlining procedures for regulation of reissues).

167. *See* 35 U.S.C.A. § 253 (West 2009) (outlining procedures for regulation of terminal disclaimers).

168. *See* 35 U.S.C.A. §§ 254-56 (West 2009) (outlining procedures for regulation of certifications of corrections).

169. *See* 35 U.S.C.A. § 302-07 (West 2009) (outlining procedures for ex parte reexamination procedures).

170. *See* 35 U.S.C.A. § 311-18 (explaining procedures for optional inter partes reexamination proceedings).

171. 203 F.3d 1305, 1311-13 (Fed. Cir. 2000).

172. *Id.* at 1313.

173. 5 U.S.C.A. § 706(2)(A) ; *Gartside*, 203 F.3d at 1311-12. As Stuart Benjamin and Arti Rai note, the Federal Circuit's contention that the "substantial evidence" standard is a more stringent one is not a well-settled

Choice of policy-making forms, then, has significant consequences for what type of judicial review is possible. Moreover, such choice of form can be abused. In particular, the USPTO has often issued significant interpretations of rules in the guise of policy guidance documents. For instance, the USPTO recently issued its *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International v. Telefex, Inc.*[174] By issuing the decision as a guidance document rather than a substantive rulemaking, the USPTO avoided judicial review under Section 553(b)(A) of the APA, which exempts "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" from its scope.[175] Notably, other agencies with a significant use of interpretative guidelines, such as the Treasury Department, also have had a difficult time reconciling their particular regime with the broader goals of administrative law.[176]

Moreover, the differences in form reflect real clashes in the values of the respective regimes. For example, in *Brand v. Miller*,[177] the Federal Circuit concluded that the members of BPAI could not rely on their own individualized "common-sense" expertise to undertake non-obviousness determinations under *KSR* because that information was not "on the written record" as required by the APA.[178] On the one hand, such a written record requirement is consistent with the APA mandate that agencies undertake their decision-making in a transparent matter.[179] On the other hand, as critics have noted, denying the examiners of the BPAI the ability to rely on internal "common-sense" judgments in making non-obviousness determinations places them at a significant disadvantage as opposed to other decision-makers, such

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question of law. Benjamin & Rai, *supra* note 3, at 291-92.

174. 72 Fed. Reg. 57526 (Oct. 10, 2007) *available at* http://www.uspto.gov/web/offices/com/sol/notices/72fr57526.pdf.

175. 5 U.S.C.A. § 553(b)(A).

176. Kristin E. Hickman, *Coloring Outside of the Lines: Examining Treasury's (Lack of) Compliance with Administrative Procedure Act Rulemaking Requirements*, 82 NOTRE DAME L. REV. 1727, 1795-99 (2007).

177. 487 F.3d 862 (Fed. Cir. 2007).

178. *Id.* at 868.

179. *See* 5 U.S.C.A. § 552 (requiring federal agencies to make various information open to the public); 5 U.S.C.A. § 552(b) (mandating that federal agencies conduct open meetings in many instances); 5 U.S.C.A. § 553 (proscribing that federal agencies open rulemakings to public comment); *see also* Martin E. Halstuk & Bill F. Chamberlin, *The Freedom of Information Act 1966-2006: A Retrospective on the Rise of Privacy Protection Over the Public Interest in Knowing What the Government's Up to*, 11 COMM. L. & POL'Y 511, 521 (2006) (explaining that Congress passed the APA in response to public demands for transparency in government and a desire to standardize agency disclosure of information).

as patent examiners and district court judges, who may also make determinations under interferences.[180]

Brand demonstrates the conflict between a standardized norm of transparency valued by the administrative regime, which may be diametrically opposed to the norm of contextual evaluation favored by the patent regime. What then are the ways—without full assimilation—that the patent state can become more reconciled to the administrative state? First, administrative law has a number of flexible doctrines that can achieve a partial reconciliation. As discussed previously, judicial review of interpretative agency decision-making can be undertaken within a persuasiveness framework.[181] The *Skidmore* persuasiveness framework has much to recommend it for use in a reconciled administrative framework. The framework covers a broad range of administrative actions that the USPTO undertakes and moreover, the multi-factor test is a contextual one that analyzes the circumstances in which agency decision-making can occur.

Second, reconciliation could involve a more nuanced appreciation of the time in which the USPTO is undertaking an administrative choice. The USPTO's ability to regulate in the post-issuance context is potentially more constrained than its ability within the pre-issuance context. Under Section 2(a), the general grant of authority, the USPTO "shall be responsible for the granting and issuing of patents."[182] The terms "granting" and "issuing" can be seen as temporal constraints upon the powers of the USPTO in so far both refer to the process of obtaining the patent. Upon issuance of the patents, the USPTO's authority is funneled through fixed avenues of administrative action such as reissue, terminal disclaimer, or certificates of correction. Thus, the specific grant of authority in Section 2(a) provides a significant limit on the authority of the USPTO to regulate patent authority. Moreover, such limits make sense when other agencies have a significant role in regulating patent law after the patent has issued. For instance, the ITC regulates—and has the power to issue precedential opinions—on potentially infringing imported items.[183] This is particularly useful in addressing the temporal context, pre- or post-issuance, in which the USPTO is undertaking

180. Robert C. Nissen & Charles L. Gholz, *Brand v. Miller Prevents Administrative Patent Judges from Using Their Common Sense in Inter Partes Proceedings*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 321, 324-25 (2008).

181. *See supra* notes 70-80 and accompanying text (explaining the *Skidmore* persuasiveness framework and its use by federal courts); *see also supra* notes 97-111 and accompanying text (advocating for the *Skidmore* persuasiveness framework to be applied to the patent regime).

182. 35 U.S.C.A. § 2(a).

183. *See* Murray, *supra* note 153, at 300 (exploring the role of the ITC in the post-issuance regulation of patents).

its decision-making action. The terrain of administrative law, then, offers a fruitful way to achieve gradual reconciliation of the two regimes. Gradual reconciliation can also be achieved in ways suggested by *Tafas*. Patent regulators and the patent community itself can become more self-conscious in how they approach administrative law. The mantra of patent execptionalism prevents a sustained assessment of how these two areas of law substantively work together.

B. Principle Two: Reconciliation Must Involve the Patent Civil Society

In *Tafas*, at least thirty-eight parties submitted briefs at the district court level (a rather remarkable number, given that this was the *initial* level of review).[184] This would generally seem as if it were a healthy development. The presence of so many amicus briefs, however, really demonstrates how distorted administrative law practice is in the current patent regime. These parties submitted amicus briefs for one simple reason: they did not have the independent ability to bring a claim under the APA. Such claims were limited by the Federal Circuit's holding in *Animal Legal Defense Fund v. Quigg* ("*ALDF*").[185] In *ALDF*, the Federal Circuit held that the plaintiffs at stake—farming associations, farmers, and animal protection groups—could not sustain either a constitutional standing challenge because of the difficulty of establishing a concrete injury in fact;[186] or even if they could, none of the claimants fell within the zone of interests protected by the Patent Act (and so therefore could not bring a claim under the APA).[187] Indeed, the Federal Circuit in *ALDF* implied that the entire statutory scheme of the Patent Act precluded third party participation under the APA.

ALDF is remarkable, then, in that it precludes interested parties from bringing challenges to a range of USPTO administrative actions. Moreover, *ALDF* is the crucial case precedent in which the Federal Circuit first outlined its argument that the USPTO authority under Section 6 did not include the power to undertake substantive rulemaking.[188] Indeed, it is the first case that *Merck* cites to in its crucial holding.[189] The Federal

184. *See supra* note 19 (listing the individuals and groups that filed amicus briefs in the *Tafas* district court case).

185. 932 F.2d 920 (Fed. Cir. 1991); *see* Murray, *supra* note 145, at 81-89 (discussing the standing issues in *ALDF*).

186. *ALDF*, 932 F.2d at 931-35.

187. *Id.* at 938-39.

188. *Id.* at 927-30.

189. *Merck*, 80 F.3d at 1549-50 (citing *ALDF*, 932 F.2d at 930). The court in *ALDF* stated that the: "authority granted in section 6 is directed to the

Circuit's holding in *ALDF*—that the USPTO did not have the right to engage in substantive rulemaking—is linked to its subsequent holding that prudential and constitutional standing should not be accorded to third parties to challenge pre-issuance rulings under the APA.[190] In light of *ALDF*, an interesting counterpoint exists to the USPTO's advocacy of a greater deference to its agency choices under the *Chevron* deference framework: if such deference is given, is the denial of constitutional and prudential standing to third parties to bring challenges to USPTO still a relevant way of viewing the patent regime? This potential broadening of third party interests suggests that ultimately, any expansive changes to the USPTO's authority should occur at the legislative branch as only Congress is in the position to contemplate such significant changes to the overall patent regime.

A principled approach to patent administrative law has to include the ability of third parties—through expanded standing—to bring claims. The failure to properly accord full standing on third parties creates a distorted administrative process. Third parties have a more significant incentive to police the administrative actors, where, unlike the issue at stake in *Tafas*, the stakes are *not* high. Third party advocate groups offer a consistent way to ensure that the administrative actor is acting in a coherent and transparent manner. For example, the USPTO's issuances of what it termed interpretative guidelines in the wake of *KSR* have had a significant impact on the subsequent examination of claims. The USPTO's classification of these rules as "interpretative rules" can be challenged under administrative law doctrine. These rules, however, were not challenged. Such a classification, however, might have been challenged if advocate groups were actually empowered to do so. The common response to active third party participation is that an increase in third party participation would significantly lessen the already compromised efficiency of the USPTO. Such a response, however, presumes that the only administrative action at stake before the USPTO is examination. As previously discussed, the USPTO is engaged in a multitude of tasks beyond examination and an active and engaged third party civil society must be necessarily engaged in ensuring that those tasks are completed. A more active recognition of third party interests would be beneficial in the work of smoothing patent law's rough edges.

'conduct of proceedings' before the Office. A substantive declaration with regard to the Commissioner's interpretation of the patent statutes . . . does not fall within the usual interpretation of such statutory language." *ALDF*, 932 F.2d at 930.

190. *Id.*

IV. CONCLUSION

In many ways, the perspectives of the USPTO's administrative authority remain stuck in the past, left in the moment of those vociferous debates in the 1930s and 1940s over its ultimate participation in the modern administrative state. The real question of *Tafas* is whether the patent administrative state, which has grown more sophisticated and complex, needs to remain stuck at that moment. While the textual ambiguity at the heart of Section 2 remains until a potential Congressional amendment, its ambiguities can be temporarily resolved by a reliance on the *Skidmore* persuasiveness framework. Moreover, the two principles outlined above—reconciling patent and administrative law, and bringing in third parties to undertake the task of that reconciliation—offer important ways in which to guide the "new normal" of the patent administrative state.